

## **REMARKS**

### **Status of the claims**

Claims 1-4 are pending in the application with claim 2 being withdrawn and claims 1 and 3-4 being amended herein. Claims 1 and 3-4 have been amended to be in proper format for US examination and no new matter has been added. Entry and consideration thereof are respectfully requested.

### **Claim objections**

Claims 1, 3 and 4 have been objected to for the noted informalities. Claims 1, 3 and 4 have been amended to be address the informalities and place the claims in proper format for consideration.

### **Rejections under 35 U.S.C. §112, 2<sup>nd</sup> paragraph**

Claims 1, 3 and 4 have been rejected under 35 U.S.C. §112, 2<sup>nd</sup> paragraph as being indefinite. Claims 1, 3 and 4 have been amended to address these issues and withdrawal of the rejections is respectfully requested.

### **Rejections under 35 U.S.C. §102(b)**

Claims 1, 3 and 4 have been rejected under 35 U.S.C. §102(b) as being anticipated by Chou et al. Chou et al. is asserted to teach an extract from *Stephaniae tetrandrae* roots that contains tetradine, fangchinoline, cyclanoline and oblongine, which can be used to modulate cardiovascular disease and inflammation. Applicants traverse this rejection and withdrawal thereof is respectfully requested. US '541 is asserted to teach an extract from *Stephaniae tetrandrae* roots that contains tetradine, fangchinoline and cyclanoline. The Examiner notes that the reference does not disclose the presence of oblongine in the extract. However, the Examiner asserts that the reference extraction method and that disclosed in the instant specification are similar enough that oblongine would also be present in the reference extract. Finally, the Examiner notes that since the alkaloids are present in *Stephaniae tetrandrae* roots they would

inherently be present in any extract made from the roots. Applicants traverse this rejection and withdrawal thereof is respectfully requested.

The instant invention, as recited in claims 1, is drawn to a specially processed extract of *Radix Stephaniae tetrandrae* (SPRST) comprising tetrandrine (Tet), fangchinoline (Fan), cyclanoline (Cyc) oblongine (Obl) alkaloids and other compounds with biological activity. The Examiner points to the disclosure in the references of extracts containing the four recited alkaloids. However, the Examiner has failed to consider the recited feature of the claims that the extract of the invention also contains other compounds with biological activity.

The present inventors have found that their extract ("SPRST") contains components that present additional to the alkaloids. This can be seen from the HPLC data of the specification. With the extract of the invention, Tet and Fan need only be present at concentrations of approximately 1.3% and 0.7%, respectively, but the potency of the extract is the same as pure Tet. However, when the same concentrations of Tet and Fan are used in the absence of the additional compounds that are present in the extract there is no anti-inflammatory effect. In addition, because of the reduced concentrations of Tet and Fan that are needed with the instant extract, the toxicity of the SPRST is much lower than when Tet and/or Fan are used in the absence of other compounds.

While the inventors have not identified the other compounds present in the SPRST, they have shown that these compounds are consistently present in the extract, i.e. one skilled in the art would be enabled from the specification to make the SPRST extract even though the additional compounds are unnamed. The SPRST extract of the invention contains the additional components that are not disclosed in Chou et al. These additional compounds result in properties of the extract that are not seen in the prior art extracts, i.e. lower toxicity and increased anti-inflammatory activity by the Tet and Fan that are present. As such, the invention is not anticipated by the reference and withdrawal of the rejection is respectfully requested.

The discussion above regarding the distinctions between the extract of Chou et al. and the SPRST extract of the instant invention are equally applicable to US '541. US '541 similarly fails to disclose or suggest the additional compounds that are present with the claimed SPRST extract. As such, US '541 does not anticipate the invention and withdrawal of the rejection is respectfully requested.

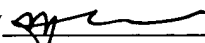
In view of the above amendment, applicant believes the pending application is in condition for allowance.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

If the Examiner has any questions concerning this application, the Examiner is requested to contact MaryAnne Armstrong, Ph.D., Reg. No. 40,069 at the telephone number of (703) 205-8000.

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Respectfully submitted,

By   
MaryAnne Armstrong, Ph.D.  
Registration No.: 40,069  
BIRCH, STEWART, KOLASCH & BIRCH, LLP  
8110 Gatehouse Road  
Suite 100 East  
P.O. Box 747  
Falls Church, Virginia 22040-0747  
(703) 205-8000  
Attorney for Applicant